Saint Louis University Institutional Review Board

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| Additional Criteria for Environmental Protection Agency (EPA) Research  (*Check if “Yes” or “N/A.” Note: all must be checked for final approval.)* | |
|  | The research includes intentional exposure of human subjects and is intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA).  *Note: IRB determinations and approval for all research intended for submission or inspection by the EPA must be submitted to the Environmental Protection Agency (EPA) Human Subjects Research Review official for final review and approval before the research can begin.* |
|  | The research does not include the intentional exposure of children, pregnant women, or nursing women to any substance.  *Note: Research conducted or supported by the EPA or intended for submission to the EPA involving exposure of the aforementioned groups to any substance is prohibited.* |
|  | The IRB has reviewed observational research involving pregnant women and fetuses using 40 CFR 26 and 45 CFR 46 Subpart B. |
|  | The research involves children and involves observational research that does not involve a greater than minimal risk, the methods of obtaining consent are clearly outlined in the protocol and follow 40 CFR 24.406. |
|  | The research involves children and involves a greater than minimal risk with the prospect of direct benefit (MUST check all):  The intervention or procedure includes direct benefit to the child or is likely to contribute to the child’s well-being.  The associated risk is justified by the anticipated benefit to the participants.  The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.  The methods of obtaining consent are clearly outlined in the protocol and follow 40 CFR 24.406. |